

REMARKS

Reconsideration and withdrawal of the rejections to the application are respectfully requested in view of the remarks herewith.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 96-124 are now pending. Claims 117-124 have been added, and claims 43-95 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally and herein presented, are and were in full compliance with the requirements of 35 U.S.C. §112. The new claims, as presented herein, are not added for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, these claims are added for clarification and to round out the scope of protection to which Applicants are entitled.

Support for the new claims is found in the claims as originally presented and throughout the specification. Specifically, support is found in cancelled claim 90, the recitations of which may be found in new claims 117-124.

II. CLAIM OF PRIORITY

The December 17, 2002 Amendment contained an amendment to the specification inserting a priority claim to U.S. Application Serial Number 09/169,178, filed October 8, 1998 which issued on August 15, 2000 as U.S. Patent Number 6,103,526, of which the present application is a continuation-in-part. The March 25, 2003 Office Action acknowledges this claim of priority.

A newly executed Declaration that includes the above-mentioned claim of priority will be filed in due course. Accordingly, it is respectfully requested that the claim of priority to USSN 09/169,178, of which the present application is a continuation-in-part, be granted, and that a corrected filing receipt be issued to make note of such additional priority claim. To the extent that a Petition is required, this paper may serve as such, and the Commissioner is authorized to charge any required petition fee to Deposit Account 50-0320.

III. THE OBJECTION TO THE SPECIFICATION IS OVERCOME

The Office Action objected to the specification because the December 17, 2002 Amendment allegedly contains new matter. Specifically, the insertion of the text known as “Example 9” is objected to. The objection is respectfully traversed.

As discussed above, the present application is a continuation-in-part of U.S. Application Serial Number 09/169,178. Furthermore, the present application incorporates by reference the text of all priority applications and all applications referenced on page 1 of the specification in their entirety, including USSN 09/169,178. The Examiner is respectfully invited to review page 1, second paragraph of the application as filed, where it is stated that USSN 09/169,178 is incorporated herein by reference.

USSN 09/169,178 contains the text known as “Example 9” in its entirety. Accordingly, Applicants hereby exercise their right to incorporate the text into the present application. Therefore, the inclusion of “Example 9” is not new matter.

Additionally, it is respectfully submitted that the amendment to the specification in the December 17, 2002 amendment did not serve to incorporate USSN 09/169,178 into the present application as USSN 09/169,178 was incorporated by reference into the present application at the time of filing. Rather, such amendment merely added the claim of priority and provided updated information regarding the application, namely information regarding the patent that issued from USSN 09/169,178.

Consequently, the text of “Example 9” is present in USSN 09/169,178 in its entirety, USSN 09/169,178 was incorporated by reference into the text of the present invention at the time of filing, and the incorporation of “Example 9” into the present application does not constitute new matter; therefore, reconsideration and withdrawal of the objection to the specification based on new matter is respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 90 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the present invention. Specifically, it is alleged that claim 90 is dependent on both a non-elected invention and a non-elected species. The rejection is respectfully traversed.

Claim 90 has been cancelled in the amendment herein, rendering the rejection moot. It is respectfully submitted that new claims 117-124 replace claim 90 and contain all of the limitations of original claim 90.

Consequently, reconsideration and withdrawal of the 35 U.S.C. §112 rejections is respectfully requested.

V. THE ART REJECTIONS ARE OVERCOME

Claims 90, 96-97, and 99-116 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary and claim 98 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary. The rejections are respectfully traversed and will be addressed collectively. As claims 117-124 contain the recitations of cancelled claim 90, which was rejected under 35 U.S.C. §102(b), the comments and remarks below may be considered to also apply to claims 117-124, such that the addition of claims 117-124 raise no further issues for examination.

*Examined
not examined
from yet?*

Quelle, with or without the evidence provided by Dorland, does not teach or suggest the presently claimed invention; and, Quelle, with or without the evidence provided by Dorland, does not provide any teaching, suggestion, motivation, or incentive to modify the cited document to arrive at the instant invention.

Initially, it is respectfully pointed out that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). It is also well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the

Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Applying the law to the instant facts, it is respectfully submitted that the instant invention is not anticipated by Quelle, *inter alia*, because Quelle does not contain a teaching of all of the elements of the instant claims. And, it is respectfully submitted that the instant invention is not rendered obvious by Quelle, as Quelle does not provide a teaching or suggestion of all of the elements of the instant claims, *inter alia*.

The present invention relates to, *inter alia*, a substantially pure, recombinant glycosylated erythropoietin, produced by a baculovirus expression system in cultured insect cells, wherein said erythropoietin has relative homogeneity or is purified to 95% or greater and said erythropoietin stimulates erythropoiesis and has an activity of at least 200,000 U/mg or of about 500,000 U/mg.

The Office Action states that Quelle relates to a "glycosylated, >99% pure, recombinant human erythropoietin produced by a baculovirus expression system, said expression system cultured in an insect cell, wherein said erythropoietin has an activity of 200,000 U/mg protein". Additionally, the Office Action points to Dorland's Illustrated Medical Dictionary to provide evidence that erythropoiesis is an inherent activity of erythropoietin. Office Action at 4.

Dorland's defines erythropoietin as "a glycoprotein hormone secreted chiefly by the kidney in the adult and by the liver in the fetus, which acts on stem cells of the bone marrow to stimulate red blood cell production (erythropoiesis)." Inherent to this definition is that erythropoiesis is an *in vivo* activity and that erythropoietin acts *in vivo* to cause erythropoiesis.

One element of the claimed invention is that the erythropoietin stimulates erythropoiesis. As discussed above, erythropoietin stimulates erythropoiesis *in vivo*, such that the erythropoietin of the present invention must be active *in vivo*. As such, the *in vivo* activity of the claimed erythropoietin is an element of the claimed present invention.

Handwritten note: } the word "in vivo" is not in Quelle ref. and is not

In contrast, the erythropoietin discussed in Quelle is described as having "little, if any, activity *in vivo*." Quelle at 654. Further, Quelle attempts to explain the "lack of *in vivo* activity" as a result of the absence of sialic acid. Quelle at 656.

Consequently, Quelle does not contain all the elements of the present invention as the erythropoietin described in Quelle admittedly has "little, if any, *in vivo* activity". As *in vivo*

activity is an element of the presently claimed invention, and Quelle's erythropoietin does not possess *in vivo* activity, the rejection under 35 U.S.C. §102(b) is improper and should be withdrawn.

Furthermore, Quelle does not contain any teaching, suggestion, motivation, or incentive to modify which would allow one of skill in the art to arrive at the present invention.

The Office Action states that it would have been obvious to further purify a "partially-purified protein/hormone". Office Action at 5. However, it is respectfully asserted that this argument is irrelevant due to Quelle's failure to teach, suggest, motivate, or provide incentive to modify the teachings of Quelle, in order to arrive at the present invention. Again, Quelle relates to a purified erythropoietin with "little, if any, *in vivo* activity." The present invention relates to, *inter alia*, a purified erythropoietin which stimulates erythropoiesis, an inherently *in vivo* activity. Accordingly, the erythropoietin of the present invention possesses *in vivo* activity, whereas the erythropoietin described by Quelle does not.

Furthermore, Quelle does not provide any teaching, suggestion, motivation, or incentive to modify the reference in order to obtain a purified erythropoietin which retains its *in vivo* activity. Additionally, Quelle does not suggest the presently claimed invention, i.e. a purified erythropoietin having *in vivo* activity, *inter alia*, or provide any expectation of success in modifying Quelle to arrive at the present invention. Accordingly, the 35 U.S.C. §103(a) rejection is improper and should be withdrawn.

Therefore, because Quelle does not contain all the elements of the presently claimed invention, and because Quelle does not provide any teaching, suggestion, motivation, or incentive to modify to allow one of skill in the art to arrive at the present invention, it is respectfully requested that the rejections under 35 U.S.C. §§ 102(b) and 103(a) be reconsidered and withdrawn.

CONCLUSION

The Amendments and remarks herein place the application in condition for allowance. An early and favorable consideration of the application on the merits, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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